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5 510(k) Summary

OCT 17 2008

510(K) Owner's Name:	Coloplast A/S
Address:	Holtedam 1 3050 Humlebaek, Denmark Establishment Registration: 9610694 Owner/Operator: 8010144
Name Of Contact Person:	Angela Byland Regulatory Affairs Manager
Phone And Fax Numbers:	Phone: (612) 287-4236 Fax: (612) 287-4138 Email: usaby@coloplast.com
Submission Date:	September 9, 2008
Trade Name:	VIRTUE™ Ventral Urethral Elevation Sling System
Common or Usual Name:	Sub-Urethral Sling System; Surgical Mesh
Classification Name:	Surgical Mesh, polymeric

Legally Marketed Device To Which Your Firm Is Claiming Equivalence:

The Coloplast VIRTUE Ventral Urethral Elevation Sling System is substantially equivalent in performance, indications, design and materials to American Medical Systems (AMS) AdVance Male Sling System cleared under premarket notification number K053371.

Description Of The Device:

The Coloplast VIRTUE Ventral Urethral Elevation Sling System consists of a polypropylene mesh with four arms. The four arms are each covered with a sleeve and a suture is affixed at each end to allow for attachment to the introducer. The introducer consists of a handle and stainless steel wireform. The device kit (implant plus introducer) is provided sterile and for single use only.

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Intended Use Of The Device:

The Coloplast VIRTUE Ventral Urethral Elevation Sling System is an implantable, suburethral support sling indicated for the treatment of male stress urinary incontinence (SUI).

Technological Characteristics Compared To Predicate Device:

The Coloplast VIRTUE Ventral Urethral Elevation Sling System is substantially equivalent in design, materials, performance characteristics, and indications to the predicate American Medical Systems (AMS) AdVance Male Sling System cleared under premarket notification number K053371.

Summary and Conclusions of The Nonclinical Tests Submitted:

Substantial equivalency is supported by bench testing compared to the predicate device and biocompatibility testing performed on the subject device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 17 2008

Coloplast Corporation
% Ms. Angela Byland
Manager, Regulatory Affairs
1499 West River Road North
Minneapolis, Minnesota 55411

Re: K082640
Trade/Device Name: VIRTUE Ventral Urethral Elevation Sling System
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: October 13, 2008
Received: October 14, 2008

Dear Ms. Byland:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

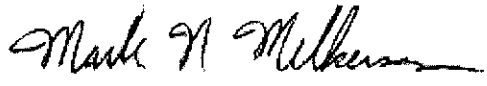
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4 Indications for Use Statement

Indications for Use

510(k) Number (if known): K082640

Device Name: VIRTUE Ventral urethral Elevation Sling system

Indications for Use:

The Coloplast VIRTUE Ventral Urethral Elevation Sling System is an implantable, suburethral support sling indicated for the treatment of male stress urinary incontinence (SUI).

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark R. Melkerson for max

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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(Posted November 13, 2003)